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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,447	08/17/2006	Osamu Tajima	049441-0144	2302
22428 7590 11/26/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
CHEN, CATHERYNE				
ART UNIT		PAPER NUMBER		
1655				
MAIL DATE		DELIVERY MODE		
11/26/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,447

Applicant(s)

TAJIMA ET AL.

Examiner

CATHERYNE CHEN

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27, 28 and 31-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 28, 31-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendments filed on Nov. 19, 2008 has been received and entered. Currently, Claims 27-28, 31-45 are pending. Claims 27-28, 31-45 are examined on the merits. Claims 1-26, 29-30 are canceled.

Election/Restrictions

Applicant's election without traverse of group II (Claims 27-28, newly added 31-45) in the reply filed on April 23, 2007 is acknowledged.

Response to Arguments

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-28, 34-37, 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourges-Sevenier et al. (WO 02/085393 A1 with US 2005/0019438 A1 as translation) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Bourges-Sevenier et al. teaches extracts from hop, where xanthohumol, isoxanthohumol (Claim 1) at 0.01 to 50 g of isoxanthohumol (Claim 4) for

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treatment of hormones related to menopause, which includes osteoporosis (paragraph 0009), where the extract can be use in dietary compositions, in the form of drinks, in food supplements (paragraph 0012).

Applicant argues that the reference does not teach isoxantholhumol as the only essential compound and other ingredients have negative impact in osteoporosis.

In response to Applicant's argument that isoxantholhumol is the only essential compound, the claim language as written only indicate that isoxantholhumol is an active ingredient; therefore, other active ingredients are possible. Moreover, the reference does recognize using isoxantholhumol for osteoporosis (paragraph 0009).

In response to Applicant's argument that other ingredients have negative impact in osteoporosis, a disclosure of the exact mechanism of action is not required. The reference specifically claims using isoxantholhumol in a composition to treat osteoporosis. The reference gives the activity and the appropriate dosage amount to treat osteoporosis. Therefore, an artisan of ordinary skill would clearly see that this reference shows that using isoxantholhumol to treat osteoporosis was known in the art at the time of the invention.

Claim Rejections - 35 USC § 103

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 27-28, 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourges-Sevenier et al. (WO 02/085393 A1 with US 2005/0019438 A1 as translation) and Erdelmeier et al. (WO 03/014287 A1 with US 2005/0042318 A1 as translation) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Bourges-Sevenier et al. teaches extracts from hop, where xanthohumol, isoxanthohumol (Claim 1) at 0.01 to 50 g of isoxanthohumol (Claim 4) for treatment of hormones related to menopause, which includes osteoporosis (paragraph 0009), where the extract can be use in dietary compositions, in the form of drinks, in food supplements (paragraph 0012). However, it does not teach ethanol extraction, heating in alkaline water under reflux, tea, milk, yoghurt, the specific amounts per day and per time.

Erdelmeier et al. teaches extracts from hop as treatment for osteoporosis (paragraph 0004), where xanthohumol is extracted with ethanol (paragraph 0010), polar solvents, preferably hot water (paragraph 0012), alkane or supercritical carbon dioxide, subsequent extraction using water and alcohols (paragraph 0018).

The references teach using a dosage of 0.003 to 0.5 mg/kg-weight, 0.01 to 100 mg/kg-body weight adult. However, the references do not specifically

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teach using all of the specific dosages claimed by applicant. The amount of a specific dosage in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The reference teaches that the dosage and administration can be varied. Thus, the reference has recognized these parameters as variables. It would have been customary for an artisan of ordinary skill to determine the optimal dosage in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

Beverages as an acceptable form of drug delivery systems. Thus, an artisan of ordinary skill would reasonably expect that all types of beverages can be used to deliver the ingredients as taught by the references. This reasonable expectation of success would motivate the artisan to use tea, milk, yoghurt as drinks in the reference composition. Thus, using tea, milk, yoghurt are considered an obvious modification of the references.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

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ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that Bourges-Sevenier et al. and Erdelmeier et al. do not teach isoxanthohumol for treating osteoporosis and the combination do not render the claimed invention obvious.

In response to Applicant's argument that Bourges-Sevenier et al. and Erdelmeier et al. do not teach isoxanthohumol for treating osteoporosis, Bourges-Sevenier et al. teaches extracts from hop, where xanthohumol, isoxanthohumol (Claim 1) at 0.01 to 50 g of isoxanthohumol (Claim 4) for treatment of hormones related to menopause, which includes osteoporosis (paragraph 0009), where the extract can be use in dietary compositions, in the form of drinks, in food supplements (paragraph 0012). Erdelmeier et al. teaches extracts from hop as treatment for osteoporosis (paragraph 0004).

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to

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do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both references teach extraction of hops for treating osteoporosis; therefore, it would be obvious to use ethanol extraction of hops, such as that taught by Erdelmeier et al. An artisan of ordinary skill would clearly expect that the ethanol extraction taught by Erdelmeier et al. would function successfully to administer the hops extract taught by Bourges-Sevenier et al. This reasonable expectation of success would motivate the artisan to modify Bourges-Sevenier et al. to include ethanol extraction of hops as an effective means to administer the hops extract.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

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/Michael V. Meller/

Primary Examiner, Art Unit 1655